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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/515,379	08/15/95	GOUGH	E ZOMD-1039

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ART UNIT	PAPER NUMBER
3311	8

DATE MAILED:

09/10/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.

08/515,379

Applicant(s)

Gough et al.

Examiner

Mike Peffley

Group Art Unit

3311



☒ Responsive to communication(s) filed on Jul 8, 1996

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-47 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-47 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The drawing(s) filed on Aug 15, 1995 is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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The applicant's preliminary amendments and comments, received July 8, 1996, have been fully considered by the examiner. The following is a first action on the merits including full consideration of the aforementioned preliminary amendments.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the image enhancement apparatus of claim 17 and the optic visualization system of claims 37 and 38 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Specification

The disclosure is objected to because of the following informalities: pages 15 through 17 disclose various features of the invention as depicted in figures 9 and 10; however, the reference numerals used in the description and those used in the figures are not the same.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 17, 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. More specifically, there is no description of the image enhancement apparatus which is used with the multiple antenna device. Also, there is no disclosure of the optic visualization system associated with the invention. While the specification does suggest that the apparatus may be used with MRI, CT or other imaging systems, there is no specific discussion of an "image enhancement apparatus" or an "optic visualization system" or their relationship with the device.

Claims 7, 10, 11, 15, 17, 18, 21, 23, 42 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is insufficient structure and/or means in claims 7, 10, 11 and 18 to support the particular electrical operation of the device. More precisely, claim 1 has been amended such that there is no energy source connected to the device. As such, it is unclear to designate a particular operation mode (i.e. bipolar/monopolar). If it is the applicant's intention to keep the energy source out of the claim language, then it is necessary to recite that the antennas are "adapted" to operate in the bipolar and/or monopolar mode. With specific regard to claim 18, the lack of an energy source in the claim language makes it unclear as to how the antennas are maintained at a desired temperature.

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Claim 15 is unclear with the recitation of the contrast agent or dye. There is no relationship between these agents and the device, particularly considering the recitation of claim 1 from which claim 15 depends.

In claim 17, it is unclear what is meant by an "image enhancement apparatus". There is no structure or means to provide an image, therefore it is not clear what purpose an image enhancement apparatus would serve.

Claims 21 and 45 are unclear with the recitation "...each of the primary or secondary antennas..". The term "each" inherently suggests that the primary and secondary antennas are being referenced making the term "or" unclear. It is apparent that the language should read "each of the primary and secondary antennas".

Claim 23 recites a first and a second secondary antenna which is somewhat unclear since claim 1 (from which claim 23 depends) only sets forth a single secondary antenna.

Finally, claim 42 is unclear with how the sensor feedback apparatus may maintain a desired temperature at the tissue, particularly since this feedback apparatus is not structurally related to the energy source which would provide the energy to control temperature.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 31, 34 and 42-46 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Desai et al ('917).

As best depicted in Figure 2a, Desai et al disclose a device which includes a primary arm (200) with a plurality of secondary arms deployed therefrom, the secondary arms being less structurally rigid than the primary arm. The primary arm includes an outer insulation, a distal energy delivery tip and openings to allow the secondary arms to be deployed. Also, Desai et al. disclose the use of temperature sensors located on the primary and/or secondary arms to monitor tissue temperature, and further disclose a feedback means to control the delivery of energy to the individual arms based on the measured temperature.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15, 17-30, 32, 33, 35, 36, 39-41 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al ('917) in view of the teaching of Lundquist et al ('677).

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Desai et al, as discussed previously, disclose a device which includes a primary arm and a plurality of secondary arms coupled to the primary arm. The secondary arms are less structurally rigid than the primary arm and may be deployed at least partially in a lateral direction from the primary arm. The arms also includes sensor means for detecting temperature, as well as a feedback system which controls the energy delivered to the arms, individually. The arms in the Desai et al invention represent RF electrode elements which are adapted to receive energy for ablating tissue. There is no specific disclosure that the electrodes are antennas, however.

It is the examiner's position that the use of an antenna as an energy delivery means would be an obvious alternative to an electrode. In support of this position, attention is directed to the Lundquist et al reference, specifically at column 3, lines 55-57. Lundquist et al teach that an ablation device may employ an RF electrode, microwave antenna or any combination thereof. Further, Lundquist et al teach of the use of providing a fluid delivery means in association with the ablation device. The examiner further maintains that the particular operation of the electrodes (i.e. bipolar and/or monopolar) would be obvious to the skilled artisan as it is very well known in the art to provide either or both modes of operation.

With respect to the limitations regarding an infusing medium, it is noted that the Desai et al primary arm is hollow and would therefore support such a use. Further, as expressed previously, Lundquist et al teach that it is well known to provide a hollow ablation device, which may be either an RF electrode or an antenna, with an infusion means. The particular type of infusion medium is deemed to be an obvious selection to the skilled artisan which would depend

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on the particular application, as the immediate specification would support. Also, the use of a non-metallic material for the antenna is deemed to be an obvious selection of material for one of ordinary skill in the art, particularly in view of the applicant's disclosure at page 10 and further in view of the fact that the applicant fails to disclose any specific material which would be non-obvious.

Finally, the particular arrangement of the primary and secondary arms as antennas is deemed to be an obvious design choice. As discussed with respect to Lundquist et al, it is known to provide a combination of RF electrodes and microwave antennas, and the only difference between an RF antenna and a microwave antenna is the frequency of the transmitted energy which would also be obvious to the skilled artisan.

In conclusion, it would have been obvious to one of ordinary skill in the art to have provided the Desai et al device with multiple antennas as the energy emitters in lieu of the RF ablation electrodes, particularly since Lundquist et al fairly teach that electrodes and antennas are readily substitutable. Further, it would have been obvious to the skilled artisan to have provided the Desai et al device with a means to provide an infusion medium in view of the teaching of Lundquist et al. Finally, the particular arrangement of the antennas would be obvious in view of the Lundquist et al teaching, and the mode of operation (i.e. bipolar and/or monopolar) are deemed to be design considerations which are well known within the art.

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Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al ('917) and Lundquist et al ('677) as applied to the claims immediately above, and further in view of the teaching of Imran ('151).

Neither the Desai et al nor the Lundquist et al reference discloses the use of a multiplexor means for multiplexing the energy delivered to the individual emitting elements (i.e. arms). Imran discloses an ablation catheter system similar in nature to Desai et al, and further specifically teaches of using a multiplexor to multiplex the signals to individual energy emitting elements.

It would have been obvious to one of ordinary skill in the art to have provided the Desai et al system, as modified by the teaching of Lundquist et al, with a multiplexor to multiplex the signals to the individual energy emitters, particularly in view of the Imran teaching.

Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al ('917) as applied to claims 31, 34 and 42-46 above, and further in view of the teaching of Hess et al ('571).

The Desai et al device has been addressed previously. This device includes a primary arm with a plurality of secondary arms which are more flexible than the primary arm. There is no teaching of providing the Desai et al device with a laser beam delivery fiber.

The Hess et al device is very much similar to the Desai et al apparatus. Both include primary arms with flexible secondary arms coupled thereto. In the Hess et al device, the primary

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arm is hollow and houses a laser beam delivery fiber (see figure 7). It is noted that the Hess et al embodiment depicted in figure 7 is very similar to the Desai et al embodiment depicted in Figure 7a.

It would have been an obvious modification for one of ordinary skill in the art to have provided the Desai et al primary arm with a laser beam fiber optic to delivery energy to tissue, particularly in view of the teaching of Hess et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Edwards et al ('267) disclose an apparatus similar to the immediately claimed invention. The Edwards et al device includes a plurality of arms defining a particular volume for ablation. The arms are antennas (RF and/or microwave) and are hollow to allow for the infusion of a treatment agent. There is no teaching of a primary arm which is more rigid than the secondary arms as is set forth in the immediate application claims.

Edwards et al ('7443) disclose another device which includes arms in the form of antennas for introduction into tissue for ablation procedures. Again, the antennas are hollow, and again there is no suggestion of a primary arm which is more structurally rigid than the secondary arms.

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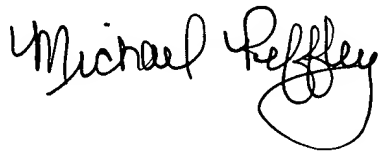
Edwards et al ('544) teach of an RF ablation apparatus which includes a plurality of probes which may be introduced into tissue. A delivery of a treatment agent is disclosed, and the energy is delivered by RF ablation electrodes, not antennas.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Peffley, whose telephone number is (703) 308-4305. The examiner can normally be reached Monday through Thursday from 7:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached at (703) 308-2713. The fax phone number for this Group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Michael Peffley/mp
September 4, 1996

A handwritten signature in black ink that reads "Michael Peffley". The signature is written in a cursive style with a large, looping "M" and a stylized "P".